UNITED STATES DISTRICT COURT **SOUTHERN DISTRICT OF TEXAS**

NEUTRINO DEVELOPMENT CORPORATION	§	
	§	
Plaintiff,	§	
	§	
versus	§	Civil Action 01-2484
	§	
SONOSITE, INC.	§	(Jury Trial)
	§	
Defendant.	§	
	§	

Neutrino's First Amended Complaint

I. The Parties

1. Plaintiff Neutrino Development Corporation ("NDC") is a Texas corporation having its principal place of business in Bellaire, Texas.

2. Defendant SonoSite, Inc. ("SonoSite") is a Washington corporation having its principal place of business at 21919 30th Drive SE, Bothell, Washington 98021-3904.

II. Jurisdiction

3. Jurisdiction exists pursuant to 28 U.S.C. § 1338(a).

III. Background

4. On April 24, 2001, U.S. Patent Number 6,221,021 ("the '021 Patent") issued, having 27 patent claims covering various embodiments of an apparatus for monitoring and/or imaging hemodynamic parameters, such as blood flow. A copy of the '021 Patent is attached as Exhibit A.

5. NDC is the assignee of all right, title and interest in the '021 Patent.

6. Defendant makes, uses, sells and offers to sell within the United States, ultrasound imaging devices that are covered by one or more claims of the '021 Patent. Such devices are, and/or have been, offered for sale under the model names SonoSite 180 PLUS,

SonoHeart PLUS, SonoSite 180, and SonoHeart. Excerpts from defendant's advertising literature depicting the SonoSite 180 and SonoSite 180 PLUS are attached as Exhibit B.

7. On or after April 24, 2001, defendant has sold or offered for sale ultrasound imaging devices that are covered by one or more claims of the '021 Patent, within the Southern District of Texas.

8. Defendant knowingly and willfully provides extensive support to its customers which induces and enables them to use SonoSite devices that are covered by one or more claims of the '021 Patent.

9. On July 24, 2001, NDC sent SonoSite a copy of NDC's Original Complaint in this lawsuit, and requested that SonoSite cease its acts of direct infringement, and its acts of inducing infringement. SonoSite has not ceased any of these infringing acts since receiving a copy of the Original Complaint in this lawsuit.

IV. Count I – Direct Infringement

10. This cause of action arises under 35 U.S.C. § 271(a).

11. NDC incorporates and realleges the allegations of paragraphs 5-9.

12. Defendant has directly infringed one or more claims of the '021 Patent. Such acts of direct infringement are willful.

13. Defendant has committed such acts of infringement within the Southern District of Texas, thereby giving rise to specific jurisdiction over defendant in this Court for this count.

14. Acts of direct infringement have damaged and will continue to damage NDC, causing irreparable harm, for which there is no adequate remedy at law. Such unlawful acts and damage will continue to occur unless enjoined by this Court.

V. Count II – Inducing Infringement

15. This cause of action arises under 35 U.S.C. § 271(b).

16. NDC incorporates and realleges the allegations of paragraphs 5-15.

17. Defendant, and/or its agents, have induced one or more persons to directly infringe the '021 Patent, in violation of 35 U.S.C. § 271(b). Such acts of inducing infringement are willful.

18. One or more acts of inducement have occurred in the Southern District of Texas since the issuance of the '021 Patent, thereby giving rise to specific jurisdiction over defendant in this Court for this count.

19. Defendant's acts of inducing infringement have damaged and will continue to damage NDC, causing irreparable harm, for which there is no adequate remedy at law. Such unlawful acts and damage will continue to occur unless enjoined by this Court.

VI. Prayer for Relief

20. NDC requests the following relief:

a. preliminary and permanent injunctive relief enjoining all acts of infringement, as provided under 35 U.S.C. § 283;

b. compensatory damages as provided under 35 U.S.C.§ 284;

c. enhancement of damages as provided under 35 U.S.C.§ 284;

d. an award of NDC's reasonable attorneys fees and costs, as provided under 35 U.S.C.§ 285 and Rule 54(d), Fed. R. Civ. P.;

e. an award of prejudgement and post-judgement interest; and

f. such other and further relief as this Court deems just and appropriate.

VII. Demand for Jury Trial

21. NDC requests a jury trial.

Respectfully submitted,

Tim Headley

Dated: **September 19, 2001**

Tim Headley
Attorney-in-Charge for
Neutrino Development Corporation
State Bar No. 09325210
Southern District Bar No. 1003
Gardere Wynne Sewell LLP
1000 Louisiana Street, Suite 3400
Houston Texas 77002-5007
Phone: 713-276 5320
Fax: 713-276-6320
Email: theadley@gardere.com

Of Counsel:

T. Michael Wall
State Bar No. 20757300
Southern District Bar No. 811
Gardere Wynne Sewell LLP
1000 Louisiana Street, Suite 3400
Houston Texas 77002-5007

CERTIFICATE OF SERVICE

I certify that on September 19, 2001, I served this document, by first class mail, on the attorney-in-charge for defendant.

Marisa Sweeney

(12) **United States Patent**
Redano

(10) **Patent No.: US 6,221,021 B1**
(45) **Date of Patent: *Apr. 24, 2001**

(54) **METHOD AND APPARATUS FOR PENILE HEMODYNAMIC STIMULATION, MONITORING, AND DRUG DELIVERY ACCELERATION**

(75) Inventor: **Richard T. Redano**, Houston, TX (US)

(73) Assignee: **Neutrino Development Corporation**, Houston, TX (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/315,867**

(22) Filed: **May 20, 1999**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/926,209, filed on Sep. 9, 1997, now Pat. No. 5,947,901.

(51) **Int. Cl.**[7] **A61B 8/06**

(52) **U.S. Cl.** **600/454**; 600/459

(58) **Field of Search** 600/437, 439, 600/453–456, 459; 601/2–3

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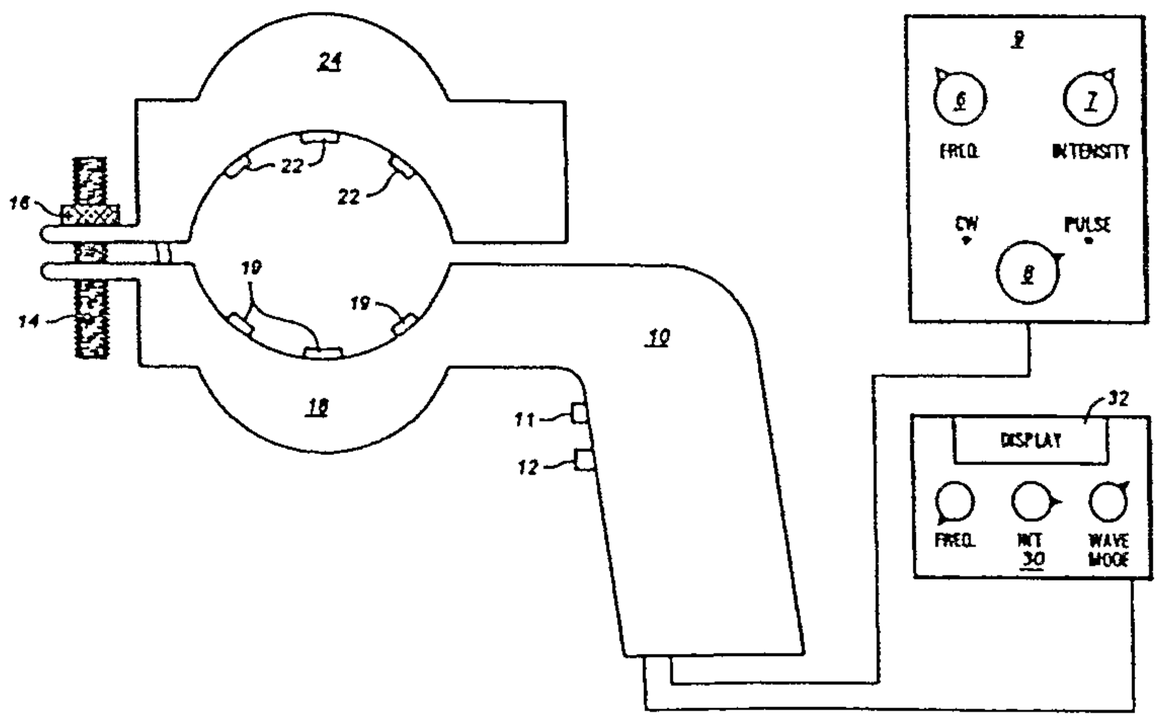
Primary Examiner—Francis J. Jaworski

(57) **ABSTRACT**

The present invention is directed toward a method and apparatus for stimulating and/or monitoring hemodynamic activity, such as blood flow, in a penis. The method of the present invention comprises the coupling of an ultrasound source to the outer surface of the penis and transmitting ultrasound energy into the penis at a sufficient frequency and intensity to increase hemodynamic activity. An apparatus is also provided for practicing the method of the present invention. The apparatus provides for position adjustment of the ultrasound transducers during the circumferential expansion of the penis resulting from increased hemodynamic activity.

27 Claims, 3 Drawing Sheets



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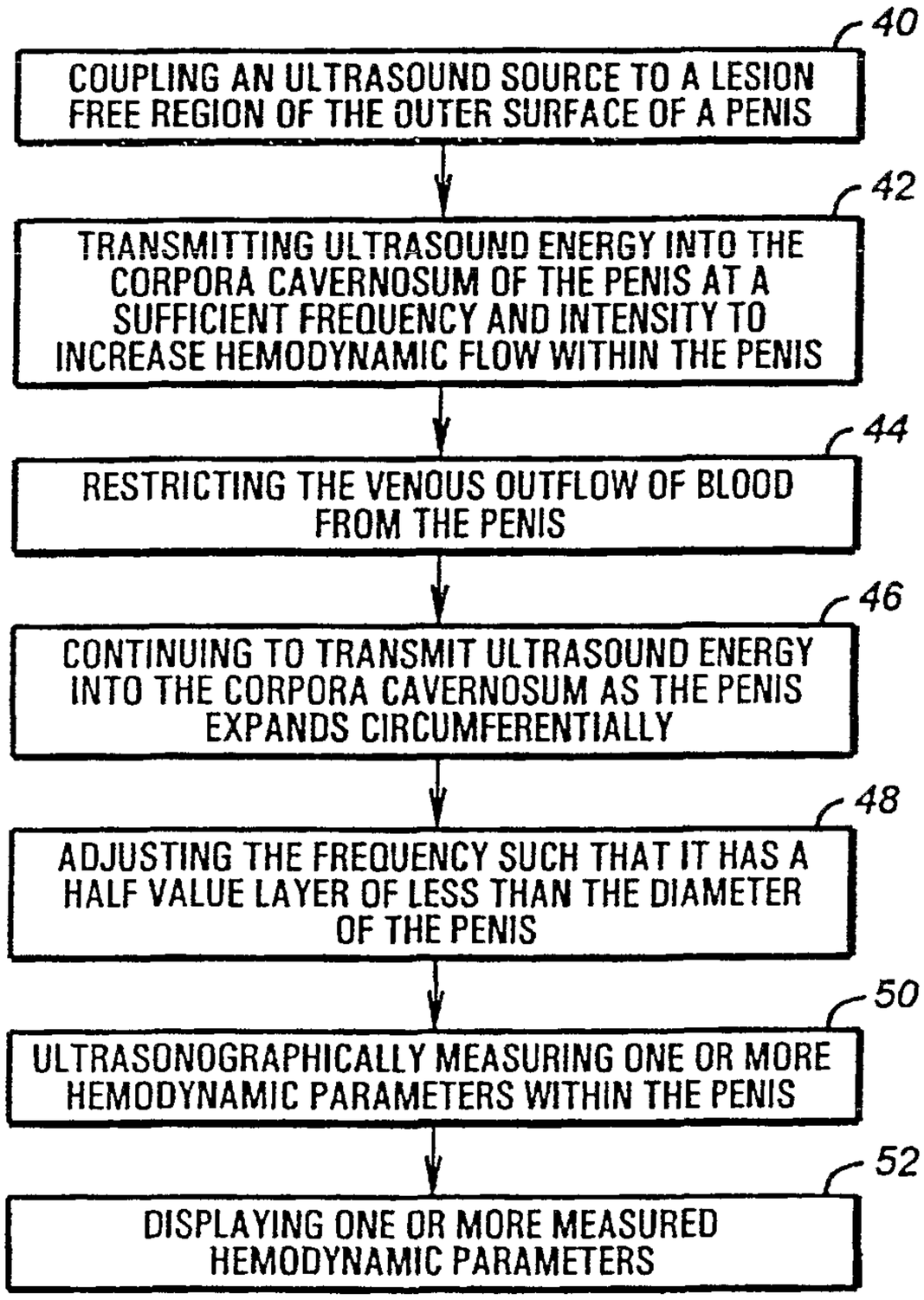

FIG. 1A

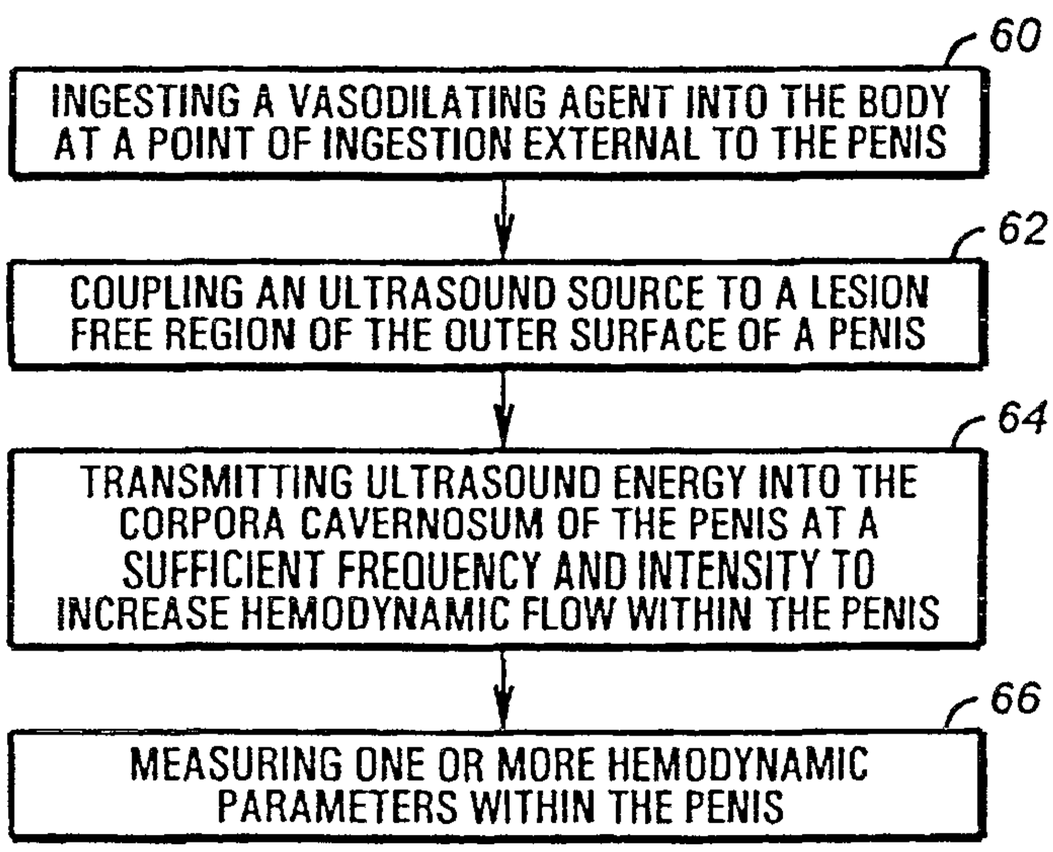

FIG. 1B

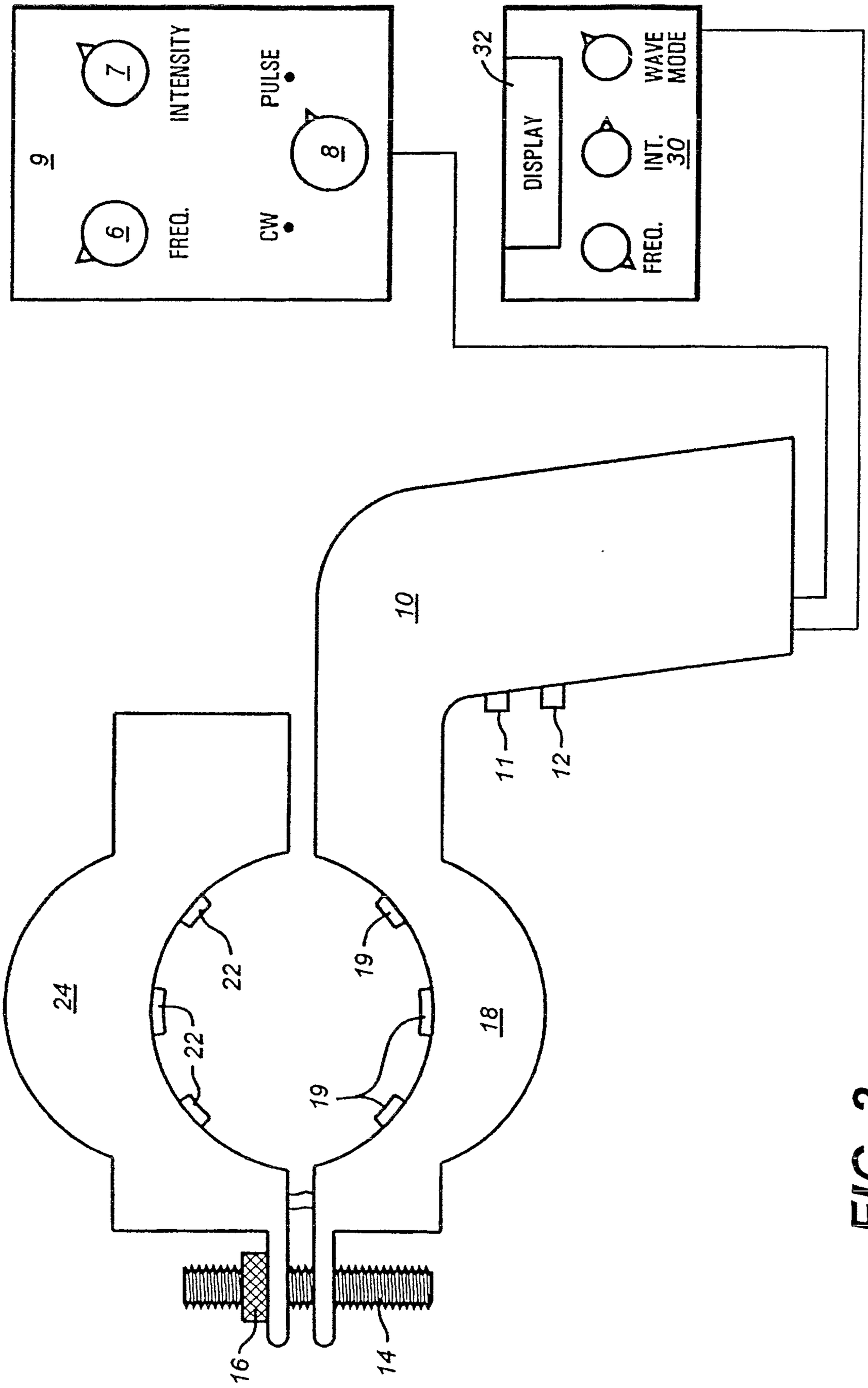

FIG. 2

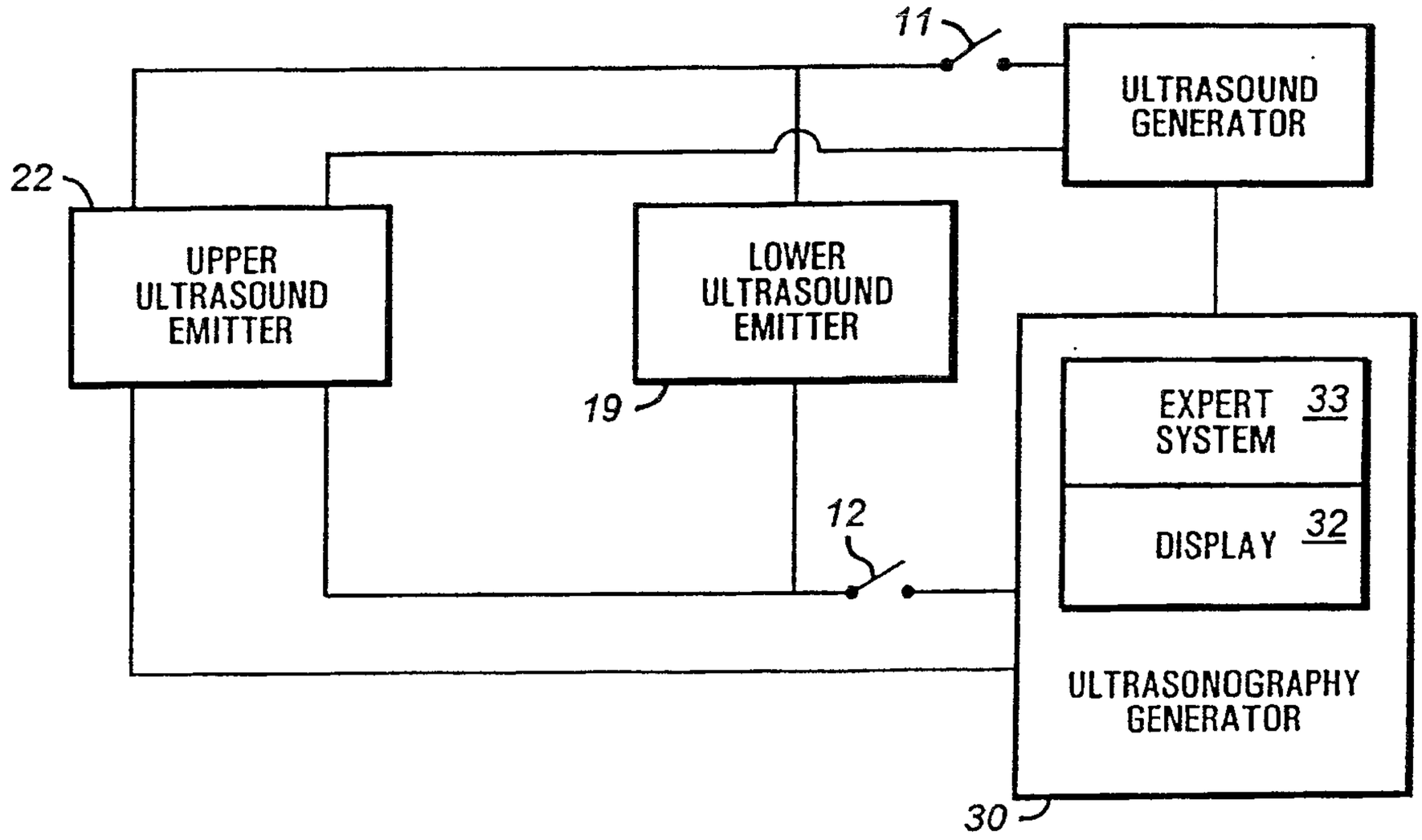

FIG. 3

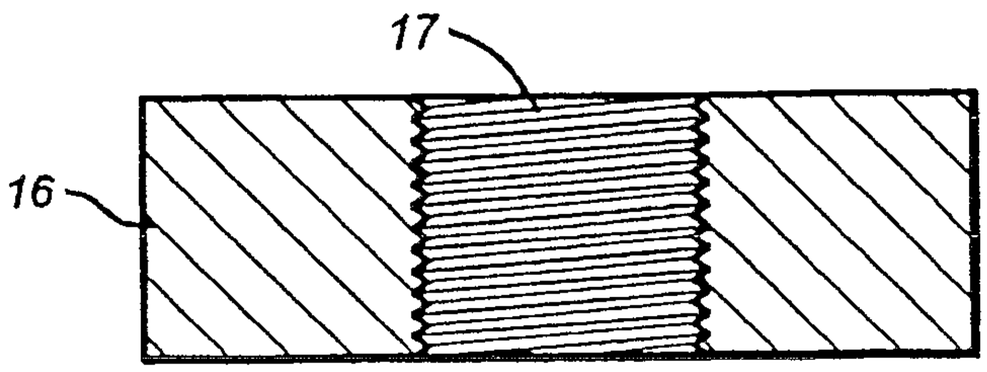

FIG. 4

METHOD AND APPARATUS FOR PENILE HEMODYNAMIC STIMULATION, MONITORING, AND DRUG DELIVERY ACCELERATION

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation in part application of application Ser. No. 08/926,209, filed on Sep. 9, 1997 now U.S. Pat. No. 5,947,901.

BACKGROUND OF THE INVENTION

1. Field of The Invention

The present invention is directed toward a method and apparatus for stimulating and/or monitoring hemodynamic activity, such as blood flow, in a penis for accelerating the delivery of drugs or pharmacological agents to the penis. The present invention comprises the coupling of an ultrasound source to the outer surface of the penis and transmitting ultrasound energy into the penis at a sufficient frequency and intensity to increase hemodynamic activity. The present invention is also directed to a method for accelerating the delivery of pharmacological agents, such as vasodilating agents, to the penis by increasing hemodynamic activity within the penis.

2. Description of the Prior Art

Erectile dysfunctionality may result from neurogenic, vasculogenic, hormonal, and/or psychogenic causes. The term "erectile dysfunctionality", as used herein, refers to the inability or impaired ability of a male patient to experience a penile erection. The urological arts have devised a number of therapies for treating erectile dysfunctionality. These therapies include psychological, pharmacological, and electrical therapies.

A method and device for electrically stimulating a penile erection is disclosed in U.S. Pat. No. 4,585,005 to Lue et al. The method disclosed in Lue includes the implantation of an electrode on the cavernous nerve. The electrodes of Lue are connected to a receiver that is subcutaneously implanted in the patient. The method and device disclosed in Lue requires surgery. Additionally, if the device disclosed in Lue malfunctions, surgery is required to remove it. Surgery is expensive and time consuming. Additionally, many patients may have emotional or psychological aversions to having electrodes implanted in their penis.

An apparatus for electrically stimulating penile tissue to cause a penile erection is disclosed in U.S. Pat. No. 5,571,118 to Boutos. Boutos discloses the use of a ring having a conductive surface that is placed on the penis and/or the scrotum. There is a risk that such a device may short circuit, if used in an electrically conductive environment, such as a hot tub. This is a major drawback of external electrical therapies, as contrasted with external ultrasound therapies. The use of ultrasound transducers on submerged patients has been applied in other nonanalogous arts, such as extracorporeal shock wave lithotripsy.

An apparatus for electrically stimulating a penile erection is disclosed in U.S. Pat. Nos. 4,542,753 and 4,663,102 to Brennan et al. Brennan discloses a body member for insertion into the rectum of a patient. The body member comprises surface mounted electrodes. Brennan teaches insertion of the body member sufficiently deep into the patient for at least one electrode to contact the prostate gland. The device disclosed by Brennan is highly invasive. Patients may experience physical discomfort from the rectal insertion of the device disclosed in Brennan.

Pharmacological therapies for erectile dysfunctionality include the injection of drugs into the penis. Such methods are disclosed in U.S. Pat. No. 5,236,904 to Gerstengerg et al. and U.S. Pat. No. 4,127,118 to Latorre. Many male patients find the thought of jabbing a hypodermic needle into their penis to be discomforting. Penile injections may also result in the buildup of scar tissue, bleeding, and persistent prolonged erection (priapism). The unacceptability of therapies requiring the intracavernosal injection of drugs into the penis is well documented in the urological arts (See U.S. Pat. No. 5,482,039 to Place et al. and U.S. Pat. No. 5,731,339 to Lowrey; and Padma-Nathan, *Treatment of Men With Erectile Dysfunction With Transurethral Alprostadil,* The New England Journal of Medicine, 336:1–7, Jan. 2, 1997).

Other pharmacological therapies for erectile dysfunctionality include delivering a drug directly into the urethra of a patient. Methods and devices for transurethral delivery of drugs into the penis are disclosed in U.S. Pat. Nos. 5,242,391 and 5,482,039 to Place et al. These transurethral drug delivery methods involve inserting a shaft into the urethra. The insertion of a shaft up the urethra may cause discomfort in many patients or be objectionable for many of the same reasons that penile hypodermic needle injections are objectionable.

Pharmacological agents for the treatment of erectile dysfunctionality, including vasodilators such as phosphodiesterase (PDE) inhibitors, or alpha adrenergic blockers, may also be delivered orally, transmucosally, transdermally, intranasally and/or rectally. Oral medications are available, pursuant to U.S. Food & Drug Administration (FDA) regulations, under the trademarks VIAGRA (a PDE inhibitor) from Pfizer, Inc. of New York, N.Y., and VASOMAX (an alpha adrenergic blocker) from Zonagen, Inc. of The Woodlands, Texas, or its licensees. Such oral medications are described in U.S. Pat. No. 5,731,339 to Lowrey and U.S. Pat. No. 5,565,466 to Gioco, et al.

Orally, transmucosally, transdermally, intranasally, and/or rectally ingested pharmacological agents for the treatment of erectile dysfunctionality must be dissolved into the blood stream and transported through the body to the penis. Methods of transporting such pharmacological agents to a desired site of effect, are disclosed in U.S. Pat. No. 5,565,466 and are incorporated herein, in their entirety. The time required for such pharmacological agents to be dissolved into the blood stream and transported to a site where they will relax the smooth muscle tissue in the corpora cavemosa, resulting in increased penile hemnodynamic activity sufficient to cause an erection (referred to herein as the "circulatory medication response time"), can be as long as one hour (see website of Zonagen, Inc at www.zonagen.com/html/sexdys.htm). This time period can be unsatisfactory to many men and their consorts, who desire spontaneity in their sexual relations.

The present invention provides an ultrasonic therapy for hemodynamic stimulation of the penis that does not require (1) the injection of drugs into the penis, (2) surgical implantation of electrodes into the penis, or (3) the insertion of electrodes into the rectum. The method of the present invention may be used in an electrically conductive medium, such as a pool or hot tub, without the short circuiting risk present in prior art methods of electrotherapy for penile dysfunctionality. The present invention may be used to reduce the circulatory medication response time by accelerating the circulation of blood comprising a vasoactive or vasodilating agent, thereby reducing its transport time.

SUMMARY OF THE INVENTION

Blood is the hydraulic driving fluid that provides the mass increase and force which result in a penile erection. Under

normal conditions, a penile erection occurs when the mass flow rate of blood into the penis exceeds the mass flow rate of blood out of the penis for a certain time interval. Vasculogenic erectile dysfunctionality may result from a restriction or blockage of blood flow into the penis or from excess blood flow out of the penis. The present invention is aimed at treating vasculogenic erectile dysfunctionality that results from inadequate blood flow into the penis. The present invention may also be used with devices intended to restrict the venous outflow of blood from the penis, such as the venous flow controller sold under the trademark ACTIS by Vivus, Inc. of Menlo Park, Calif.

The present invention provides a method for stimulating hemodynamic activity within a penis. The first method step of the present invention is coupling an ultrasound source to a penis. Genital lesions, such as warts or herpes simplex Type-2 lesions, can absorb and/or attenuate ultrasound thereby reducing the therapeutic effectiveness of the present invention. Accordingly, in a preferred embodiment, the ultrasound source is coupled to a lesion free region of the outer surface of a penis.

The second method step of the present invention is transmitting ultrasound energy into the corpora cavernosum of the penis at a sufficient frequency and intensity to increase hemodynamic flow within the penis. The frequency used is a function of the depth of desired penetration into the corpora cavernosum.

Initially, a frequency in the range of 2.5–3.5 MHz is desirable. As hemodynamic activity in the penis increases and the penis expands circumferentially, it is desirable to reduce the frequency of ultrasound energy from the initial frequency to a reduced frequency in the range of 1.8–2.5 MHz. The precise values of initial and reduced frequencies will be a function of the diameter of the penis being treated.

A portion of the ultrasound energy transmitted into the body is converted to thermal energy. The increased blood flow resulting from the use of the present invention provides a thermal transport medium for transporting and dispersing thermal energy introduced from the transmission of ultrasound energy. This thermal transport helps to minimize localized temperature increases within the penis. In a preferred embodiment, the ultrasound energy is emitted from one or more ultrasound transducers housed within a portable housing. Localized temperature increases can be further minimized by moving the portable housing relative to the penis being treated so as to disperse the transfer of thermal energy in the corpora cavernosum.

The present invention also provides a method for monitoring the effect of the stimulation therapy of the present invention. The present invention also includes ultrasonographically measuring one or more hemodynamic parameters within the penis. These hemdynamic parameters may include blood flow velocity, blood pressure, and/or blood temperature. The measured hemodynamic parameters can be graphically displayed to provide a real time indication of hemodynamic and/or thermal-hydraulic parameters within the penis. The measured hemodynamic parameters may be transmitted to a remote terminal for analysis by a remotely located health care professional. Alternatively, the measured hemodynamic parameters may be analyzed by an expert system located either remotely or with the patient.

The present invention is also directed toward an apparatus for stimulating hemodynamic activity within a penis. The apparatus of the present invention comprises an ultrasound generator, and a portable housing coupled to the ultrasound generator. The housing comprises at least one ultrasound trigger and a first transducer mounting assembly. The invention further comprises a position adjuster coupled to the first transducer mounting assembly and a second transducer mounting assembly mounted across from the first transducer mounting assembly. The second transducer mounting assembly is coupled to the position adjuster.

A first ultrasound emitter is mounted in the curved lower transducer mounting assembly. The first ultrasound emitter is connected to the ultrasound trigger and to the ultrasound generator. A second ultrasound emitter is mounted in the curved second transducer mounting assembly. The second ultrasound emitter is connected to the ultrasound trigger and to the ultrasound generator. The apparatus of the present invention may also be used to ultrasonographically measure one or more penile hemodynamic parameters.

DESCRIPTION OF THE DRAWINGS

FIG. 1A is a block diagram of a first method embodiment of the present invention.

FIG. 1B is a block diagram of a second method embodiment of the present invention.

FIG. 2 is a front view of a first apparatus embodiment of the present invention.

FIG. 3 is a block diagram of a second apparatus embodiment of the present invention.

FIG. 4 is a side cross sectional view of the rotatable adjusting wheel of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The apparatus of the present invention comprises an ultrasound generator 9 and a portable housing 10 coupled to the ultrasound generator, as shown in FIG. 2. As shown in FIG. 2, control mechanisms for regulating the transmission of ultrasound energy from the ultrasound generator are mounted on body 9, which is sized to be grasped or held in a user's hand. In a preferred embodiment, these control mechanisms include knob-like fixtures 6–7 which may be adjusted to regulate or control the frequency or intensity of ultrasound energy emitted by the ultrasound generator. The portable housing comprises a first transducer mounting assembly 18. In a preferred embodiment, the lower transducer mounting assembly is curved. An ultrasound trigger 11 is mounted in the housing and electrically coupled to the generator. The ultrasound trigger 11 is a triggering mechanism that can be actuated to cause ultrasound energy to be transmitted from the ultrasound source or emitters, as shown in FIGS. 2 and 3.

In a preferred embodiment, the ultrasound generator is capable of selectively generating pulsed or continuous wave ultrasound energy. This selective generation may be accomplished by a control knob or switch 8, as shown in FIG. 2. In a preferred embodiment, the ultrasound generator further comprises frequency controls 6 and intensity controls 7, as shown in FIG. 2. In a preferred embodiment, the ultrasound generator is capable of generating ultrasound energy within a frequency range of 1.8–3.5 MHz and within an intensity range of 1.0–2.0 watts/square centimeter.

A position adjuster is coupled to the first transducer mounting assembly. In the preferred embodiment shown in FIGS. 2 and 4, the adjuster comprises a threaded rod 14 and a rotatable adjusting wheel 16, comprising a centrally located female threaded channel 17. The channel threadably engages the rod such that when the wheel is rotated, the rod is axially displaced.

It is known in the ultrasound arts that a satisfactory ultrasound coupling is necessary for effective delivery of ultrasound energy to a patient for therapeutic or diagnostic purposes. The position adjuster provides a mechanism for maintaining a satisfactory ultrasound coupling as the penis expands circumferentially as a result of increased hemodynamic activity. As shown in FIG. 2, the position adjuster can be used to control the separation distance between the first and second mounting assemblies.

The position adjuster also makes the present invention suitable for use with different patients having varied physical sizes.

The apparatus and method of the present invention may be practiced by the patient, after proper training, without assistance from another person. In the preferred embodiment shown in FIG. 2, the portable housing has a pistol type grip, thereby allowing the user to operate the trigger or triggers with one hand, while manipulating the position adjuster with the other hand, as needed to maintain a suitable ultrasound coupling during penile expansion. As shown in FIG. 2, the portable housing **10** is sized to be grasped or held in a user's hand. The placement of the triggers and axial position adjuster on opposite sides of the housing facilitates the user's ability to easily use both hands to simultaneously manipulate the trigger and the position adjuster.

The invention further comprises a second transducer mounting assembly **24** mounted across from the first transducer mounting assembly. As shown in FIG. 2, the position adjuster permits the distance between housing **10** and mounting assembly **24** to be adjusted by the user using one hand. In the preferred embodiment shown in FIG. 2, the mounting assembly **24** is moveably connected to the housing **10**. In a preferred embodiment, the second transduced mounting assembly is mounted in alignment with the first transducer mounting assembly. In another preferred embodiment, the second transducer mounting assembly is curved. The second transducer mounting assembly is coupled to the position adjuster. The radii of curvature of the first and second transducer mounting assemblies are sized such that the first and second transducers can be coupled to the outer surface of a penis.

A first ultrasound emitter **19** is mounted in the first transducer mounting assembly. The first transducer is connected to the ultrasound trigger and to the ultrasound generator. Electrical and/or electronic circuitry suitable for connecting ultrasound transmitters to an ultrasound generator are described in the following U.S. Pat. Nos. 3,735,756 to Richards; U.S. Pat. No. 5,578,060 to Pohl et al.; and U.S. Pat. No. 4,484,569 to Driller et al. The full disclosures of these U.S. Patents is incorporated herein by reference.

A second ultrasound transducer **22** is mounted in the second transducer mounting assembly, as shown in FIG. 2. The second ultrasound emitter is connected to the ultrasound trigger and to the ultrasound generator. In a preferred embodiment, the first and second ultrasound emitters comprise a multiplicity of transducers, as shown in FIG. 2.

In the preferred embodiment shown in FIGS. 2–3, the invention further comprises an ultrasonography generator **30** connected to at least one transducer in each transducer mounting assembly and an ultrasonography trigger **12** mounted in the portable housing and connected to the ultrasonography generator. The ultrasonography trigger **12** is a triggering mechanism that can be actuated to cause ultrasound energy to be transmitted from the ultrasonography generator and through the ultrasond source or emitters, as shown in FIGS. 2 and 3. In a preferred embodiment the ultrasonography generator and the ultrasound generator are each connected to at least two ultrasound transducers in each of the transducer mounting assemblies. In a preferred embodiment the ultrasonography generator is a doppler ultrasound unit.

The ultrasonography generator is suitable for monitoring penile hemodynamic parameters, such as blood flow. Ultrasonographic apparatus suitable for use with the present invention are disclosed in the following U.S. Pat. No. 4,612,937 to Miller; and U.S. Pat. No. 4,334,543 to Fehr. The full disclosures of these two patents are incorporated herein by reference. In a preferred embodiment, the ultrasonography generator may comprise a display **32** for displaying measured hemodynamic parameters and/or an expert system **33** capable of analyzing measured hemodynamic parameters. As shown in FIGS. **2** and **3**, the display is located or mounted in a portable unit, such as the ultrasonography generator. As shown in FIG. **2**, the ultrasonography generator unit **30** is sized to be grasped or held in a user's hand. In the preferred embodiment shown in FIG. **3**, the system **33** is physically housed or located within the ultrasonography generator unit. In the preferred embodiment shown in FIG. **2**, the ultrasonography generator unit comprises control mechanisms for regulating the transmission of ultrasound energy. In a preferred embodiment, these control mechanisms include rotatable knobs which may be adjusted to regulate or control the frequency, intensity, or wave mode of ultrasound energy emitted by the ultrasonography generator. The expert system is capable of comparing one or measured hemodynamic parameters to preestablished parameter limits, such as maximum blood pressure or maximum blood temperature. The expert system is further capable of generating an instruction to the user to stop ultrasound therapy if predetermined parameter limits are exceeded. These instructions may be generated via the display on the ultrasonography generator or by other visual or audible means of communication. The display of instructions stored in the expert system is an example of the ability of the display to allow the user to view stored information.

In another embodiment, the expert system is capable of generating an open circuit signal to the ultrasound generator in the event that preestablished limits are exceeded for selected hemodynamic parameters. In this embodiment, the expert system functions as a control circuit for the ultrasound generator. In a preferred embodiment, measured hemodynamic parameter data may be transmitted to a remote location by a variety of data transmission means, including telephone lines and wireless communication.

The present invention also provides a method for stimulating hemodynamic activity within a penis, as shown in FIGS. 1A–1B. The method comprises coupling an ultrasound source to the outer surface of a penis, as shown in block **40** of FIG. 1A. In a preferred embodiment the source of ultrasound energy is coupled to a lesion free region on the outer surface of the penis. In a preferred embodiment the source of ultrasound energy comprises at least two ultrasound transducers, placed on opposite sides of the penis, as shown in FIG. 2. In another preferred embodiment the source of ultrasound energy comprises a portable housing comprising the transducers.

The method further comprises transmitting ultrasound energy into the corpora cavemosum of the penis at a sufficient frequency and intensity to increase hemodynamic flow within the penis, as shown in block **42** of FIG. 1A. It is known in the ultrasound arts that 1 MHz ultrasound has a half value layer of 3.0 cm in muscle, while 3 MHz ultrasound has a half value layer of 1.0 cm in muscle. The term

"half value layer", as used herein refers to the distance that ultrasound energy travels in a medium before half of the energy is absorbed. The half value layers of various ultrasound frequencies in muscle are disclosed in U.S. Pat. No. 5,413,550 to Castel. It is desirable that the frequency used be such that its half value layer will be less than the diameter of the penis being treated. In a preferred embodiment of the present invention, the frequency is adjusted such that it has a half value layer of less than the diameter of the penis being treated, as the penis expands circumferentially, as shown in blocks **46** and **48** of FIG. **1**A. In a preferred embodiment, the ultrasound energy should be applied at an intensity or power density of 1.0–2.0 watts/square cm.

The transmission of ultrasound energy may be either pulsed or continuous. In a preferred embodiment the invention further comprises restricting the venous outflow of blood from the penis, as shown in block **44** of FIG. **1**A.

In another preferred embodiment the invention further comprises ultrasonographically measuring one or more hemodynamic parameters within the penis, as shown in blocks **50** and **66** of FIGS. **1**A and **1**B, respectively. In a preferred embodiment, the ultrasonographic measuring may be performed with a doppler ultrasound unit.

In a preferred embodiment the ultrasonographic measuring comprises a measurement of blood flow velocity or blood pressure. In another preferred embodiment the transmitting and measuring steps are performed in alternating series. In a preferred embodiment, the invention further comprises displaying said measured hemodynamic parameters, as shown in block **52** of FIG. **1**A.

The present invention is also directed to method for accelerating the delivery of a vasodilating agent to produce a penile erection as shown in FIG. **1**B. This embodiment of the invention comprises ingesting a vasodilating agent into the body at a point of ingestion external to the penis, as shown in block **60** of FIG. **1**B. In a preferred embodiment, the vasodilating agent is a PDE inhibitor or an alpha adrenergic blocker. In another preferred embodiment, the vasodilating agent is phentolamine mesylate, phentolarnine hydrochloride, phenoxybenzamine yohimbine, organic nitrates, thymoxamine, imipramine, verapamil, isoxsuprine, naftidrofuiyl, tolazoline, or papaverine. In a preferred embodiment the ingesting is transmucosal, transdermal, intranasal, or rectal ingesting. Transmucosal, intranasal, oral, and rectal ingesting are examples of ingesting that occur at a location that is external to, and other than, the penis. In another preferred embodiment, the ingesting is oral.

The invention further comprises coupling an ultrasound source to a lesion free region of the outer surface of a penis, as shown in block **62** of FIG. **1**B. The invention further comprises transmitting ultrasound energy into the corpora cavernosum of the penis at a sufficient frequency and intensity to increase hemodynamic flow within the penis, as shown in block **64** of FIG. **1**B. Because the ultrasoumd source is coupled to a lesion free region of the outer surface of the penis, ultrasoond energy transmitted from the source is transmitted through the lesion free region of the penis. This step is a preferred embodiment of increasing hemodynmic activity within the patient's body.

The embodiments of the invention disclosed herein are illustrative and explanatory. Various changes in size, shape, material, as well as in the details of construction illustrated herein may be made without departing from the scope of the invention.

What is claimed is:

1. An apparatus for a user to monitor hemodynamic parameters when the user is grasping the apparatus housing in one hand, comprising:

a. an ultrasonography generator comprising a display capable of displaying at least one measured hemodynamic parameter;

b. a portable housing sized to be grasped in a user's hand

c. a triggering mechanism mounted in said housing and connected to said generator; said triggering mechanism being capable of actuating said generator;

d. a transducer mounting assembly moveably connected to said housing such that the distance between said assembly and said housing can be adjusted by a user using only one hand, said assembly comprising a curved surface; and

e. at least two ultrasound emitters mounted in said assembly along a curved path and connected to said triggering mechanism.

2. The apparatus of claim **1**, wherein said generator is a doppler ultrasound unit.

3. The apparatus of claim **2**, wherein said display is capable of displaying blood flow.

4. The apparatus of claim **1**, wherein said generator further comprises a system capable of analyzing measured hemodynamic parameters, said system being physically located within said generator.

5. The apparatus of claim **4**, wherein said system is capable of generating a signal to control the operation of said generator.

6. The apparatus of claim **5**, wherein said system is further capable of generating an instruction to the user.

7. The apparatus of claim **4**, wherein said system is capable of transmitting measured hemodynamic data to a location that is remote from said apparatus.

8. An apparatus capable of monitoring hemodynamic parameters, comprising:

a. a portable body sized to be hand held;

b. an ultrasonography generator mounted in said body and capable of measuring one or more hemodynamic parameters, said generator comprising a display capable of displaying at least one measured hemodynamic parameter;

c. a curved transducer mounting assembly moveably connected to said body such that the distance between said assembly and said body can be adjusted by a user using only one hand;

d. at least two ultrasound emitters mounted in said assembly along a curved path; and

e. a triggering mechanism connected to said emitters and to said generator.

9. The apparatus of claim **8**, further comprising at least two rotatable control mechanisms mounted on said body and coupled to said generator to regulate the transmission of ultrasound energy.

10. The apparatus of claim **9**, wherein said body comprises at least three rotatable control knobs.

11. The apparatus of claim **8**, wherein said generator is a doppler ultrasound unit.

12. The apparatus of claim **11**, wherein said display is capable of displaying blood flow.

13. The apparatus of claim **8**, wherein said generator further comprises a system capable of analyzing measured hemodynamic parameters, said system being housed within said body.

14. The system of claim 13, wherein said system is further capable of generating an instruction to the user.

15. A hand held apparatus for displaying measured hemodynamic parameters, comprising:

a. an ultrasonography generator comprising a display capable of displaying at least one measured hemodynamic parameter;

b. a portable housing sized to be grasped in a user's hand

c. a triggering mechanism mounted in said housing and connected to said generator; said triggering mechanism being capable of actuating said generator;

d. a transducer mounting assembly moveably connected to said housing such that the distance between said assembly and said housing can be adjusted by a user using only one hand; and

e. at least one ultrasound emitter mounted in said assembly connected to be actuatable by said generator.

16. The apparatus of claim 15, wherein said generator is a doppler ultrasound unit.

17. The apparatus of claim 16, wherein said display is capable of displaying blood flow.

18. The apparatus of claim 15, wherein said generator further comprises a system capable of analyzing measured hemodynamic parameters.

19. The apparatus of claim 15, wherein said generator is a portable unit comprising at least two control knobs for regulating the transmission of ultrasound energy.

20. A hand held apparatus capable of displaying measured hemodynamic parameters, comprising:

a. a portable body sized to be hand held;

b. an ultrasonography generator mounted in said body and capable of measuring one or more hemodynamic parameters, said generator comprising a display capable of displaying at least one measured hemodynamic parameter;

c. a transducer mounting assembly moveably connected to said body such that the distance between said assembly and said body can be adjusted by a user using only one hand;

d. at least one ultrasound emitter mounted in said assembly; and

e. a triggering mechanism connected to said generator and capable of actuating said generator.

21. The apparatus of claim 20, wherein said generator further comprises a system capable of analyzing measured hemodynamic parameters, said system being housed within said body.

22. The apparatus of claim 21, wherein said system is capable of generating an instruction to the user.

23. The apparatus of claim 20, wherein said generator is a doppler ultrasound unit.

24. The apparatus of claim 23, wherein said display is capable of displaying blood flow.

25. A hand held ultrasound imaging system for displaying hemodynamic parameters, comprising:

a. a portable body comprising a top surface, said body being sized to be hand held;

b. an ultrasonography generator mounted in said body and capable of measuring one or more hemodynamic parameters, said generator comprising a display capable of displaying at least one measured hemodynamic parameter, said display being mounted in the top surface of said body;

c. a transducer mounting assembly moveably connected to said body such that the distance between said assembly and said body can be adjusted by a user using only one hand;

d. at least one ultrasound emitter mounted in said assembly; and

e. a triggering mechanism connected to said generator and capable of actuating said generator.

26. The apparatus of claim 25, wherein said generator is a doppler ultrasound unit and said display is capable of displaying blood flow.

27. The apparatus of claim 26, wherein at least two ultrasound emitters are mounted in said assembly.

* * * * *

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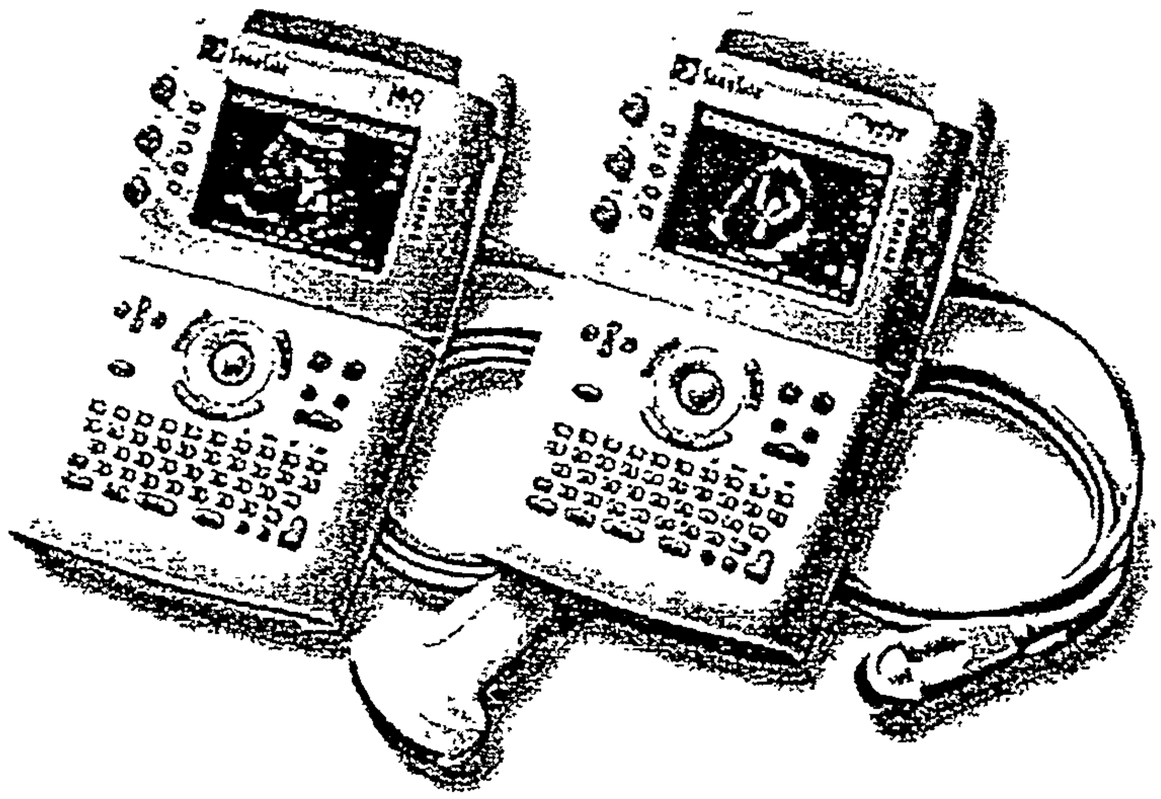

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- Directional Color Power Doppler
- Color Power Doppler
- Tissue Harmonic Imaging
- M-mode
- ECG Capability
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SYSTEM SPECIFICATIONS

Clinical Applications
- Gynecology and Obstetrics
- Labor and Delivery
- Emergency Medicine
- Urology
- Abdominal Imaging
- Cardiology

Imaging Modes
- 2D
- Zoom
- Narrow imaging sector
- Color Power Doppler
- PowerMap™ Directional Color Power Doppler
- System optimization presets for different patient body types

Physical Characteristics
- Height: 13.3 in (33.8 cm)
- Width: 7.6 in (19.3 cm)
- Depth: 2.4 in (6.1 cm)
- Weight: 5.4 lb (2.4 kg) with one transducer attached

Transducers
- Lightweight with rapid, pinless connection
- C60/5-2: 60-mm broadband (5-2 MHz) curved array for general-purpose abdominal, obstetric, and gynecologic applications
- ICT/7-4: 11-mm broadband (7-4 MHz) intracavitary array for gynecologic, obstetric, and urologic applications
- C15/4-2: 15-mm broadband (4-2 MHz) array for transthoracic and abdominal imaging

User Interface
- Controls: Color Power Doppler, near gain, far gain, overall gain, save, print, freeze, cine review, text/picto, select, measure, optimize, depth, zoom, patient
- Narrow imaging sector feature in both 2D and PowerMap color modes
- User-defined labels via function keys
- Integrated 5-in (12.7-cm) TFT color Liquid Crystal Display with brightness and contrast controls
- Integrated trackball for navigation
- Alpha-numeric keyboard

System Parameters
- System dynamic range: approximately 140 dB
- Frame rate: up to 100 frames/second

Image Storage and Cine
- Storage: internal 50 image memory for off-line printing and review
- Cine: images retained for frame-by-frame viewing

Clinical Analysis Package
- OB calculations via standard tables
- Integrated patient exam reporting
- Cardiac calulation package

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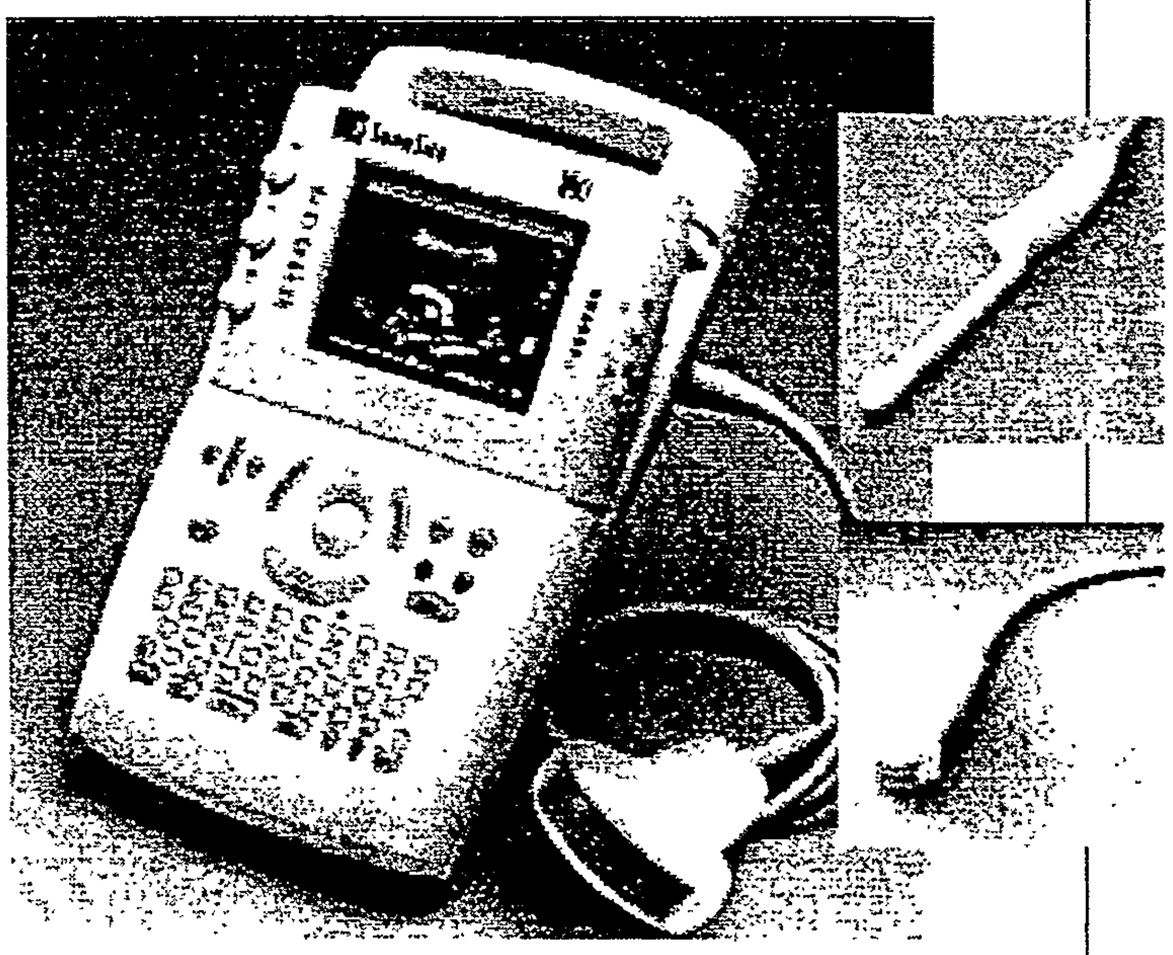

Measurement Tools
- Two sets, distance calipers
- Ellipse for area and circumference measurements

Power
- Operates via battery or AC power
- Battery: rechargeable lithium ion
- AC: via universal power adapter, 100-240 VAC, 50-60 Hz

Display Annotation
- Text and pictograms

Peripheral Connections
- Composite video output (NTSC/PAL) to videocassette recorder, video printer, or external monitor

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SonoSite, Inc.
19807 North Creek Parkway, Suite 200, Bothell, Washington USA 98011-8214
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